



10-20-04

JFW  
PATENT

ATTORNEY DOCKET NO. 007U/

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF MAILING

I hereby certify under 37 C.F.R. 1.10 that this correspondence is being deposited with the United States Postal Service as Express Mail Label No. EV 493188602 US with sufficient postage on the date indicated below and in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

[ X ] If checked, two copies of this correspondence are enclosed.

Date of Deposit: 10-19-2004

Dawn M. Janelle  
Signature

Dawn M. Janelle  
Printed name of person mailing correspondence

Applicant:	COY, David H. et al.	Art Unit:	1614
Serial No.:	10/788,563	Examiner:	Unknown
Filed:	February 27, 2004		
Title:	OCTAPEPTIDE BOMBESIN ANALOGS		

**INFORMATION DISCLOSURE STATEMENT AND AUTHORIZATION TO  
CHARGE DEPOSIT ACCOUNT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

- [ ] under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)
- [ X ] under 37 CFR 1.97(b), or  
(Whichever occurs last of the following: within three months of filing national application; within three months of date of entry of the national stage in international application; before the mailing date of first office action on the merits; or before the mailing of a first Office action after the filing of a request for continued examination)
- [ ] under 37 CFR 1.97(c) together with either:
- [ ] a Statement under 37 CFR 1.97(e), as checked below, or
- [ ] a \$180.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- [ ] under 37 CFR 1.97(d) together with:
- [ ] a Statement under 37 CFR 1.97(e), as checked below, and
- [ ] a Petition under 37 CFR 1.97(d)(2), and
- [ ] a \$130.00 petition fee set forth in 37 CFR 1.17(i).  
(Filed after final action or notice of allowance, whichever occurs first, but before payment of the issue fee)
- [ ] Applicant requests that the attached IDS and cited reference(s) [ ] be placed in the application filewrapper.  
(Filed after payment of issue fee)
- [ X ] Some of the listed references were cited in a European Search Report in a counterpart European application or cited in a communication from a foreign patent office in a counterpart foreign application.

- ☐ Enclosed herewith is form PTO/1449 (1 page; reproduced form), with a copy of each reference noted thereon.
- ☒ Enclosed herewith is form PTO/1449 (9 pages; reproduced form), with a copy of selected references noted thereon. This application was filed after June 30, 2003 and as such, copies of any United States Patent or Patent Publications are not enclosed.
- ☒ Copies of reference(s) AB, AC, AD, AE, AF, AH, AI, AJ, AK, AM, AN, AO, AR, AS, AT, AX, BA, BC, BG, BI, BK, BL, BN, BO, BS, BX, BY, BZ, CA, CC, CD, CE, CF, CG, CH, CI, CL, CM, CN, CO, CP, CQ, CR, CS, CU, CW, CY, DB, DE, DF, DG, DH, DN, DO, DP, DQ, DS, DU, DW, DX, DY, EA, EC, ED, EF, EG, EH, EI, EJ, EL, EN, EO, EQ, ER, ES, ET, and EW noted on the enclosed form PTO/1449 were previously cited by or submitted to the Patent and Trademark Office in connection with U.S. Application Serial No. 09/260,846 (now issued as U.S. Patent No. 6,307,017), from which the present application claims benefit under 35 U.S.C. § 120 (37 C.F.R. 1.98(d)). Applicants request that copies of art in U.S. Application Serial No. 09/260,846 cited on the enclosed PTO/1449 form be transferred to the present U.S. Application Serial No. 10/788,563.
- ☒ Copies of reference(s) AL, AP, AQ noted on the enclosed form PTO/1449 were previously cited by or submitted to the Patent and Trademark Office in connection with U.S. Application Serial No. 08/337,127 (now issued as U.S. Patent No. 5,877,277), from which the present application claims benefit under 35 U.S.C. § 120 (37 C.F.R. 1.98(d)). Applicants request that copies of art in U.S. Application Serial No. 08/337,127 cited on the enclosed PTO/1449 form be transferred to the present U.S. Application Serial No. 10/788,563.
- ☒ Copies of reference(s) DI and DL noted on the enclosed form PTO/1449 were previously cited by or submitted to the Patent and Trademark Office in connection with U.S. Application Serial No. 07/502,438 (now issued as U.S. Patent No. 5,084,555), from which the present application claims benefit under 35 U.S.C. § 120 (37 C.F.R. 1.98(d)). Applicants request that copies of art in U.S. Application Serial No. 07/502,438 cited on the enclosed PTO/1449 form be transferred to the present U.S. Application Serial No. 10/788,563.

Concise Explanation Requirement (non-English references):

- ☒ The "concise explanation" requirement for reference(s) [BL, BM, BN and BO] under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
  - ☐ the explanation provided in the Specification.
  - ☐ submission of the enclosed International Search Report.
  - ☐ the enclosed English language equivalent documents wherein BL corresponds to EP 347802, BM corresponds to WO 89/02897, BN corresponds to EP 345 990 and BO corresponds to EP 434 979.

It is requested that the information disclosed herein be made of record in this application, and that the references listed on the enclosed form PTO/SB/08B appear under the "References Cited" heading of any Patent which issues from this application, (MPEP 1302.12).

Statement Under 37 CFR 1.97(e):

- ☐ Each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Method of payment:

- [ ] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply.
- [X] No fee is believed to be due for this submission. However Applicant(s) hereby authorize the Commissioner to charge any fees that may be deemed to be due or to credit any overpayment to Deposit Account No. 50-0590. Two copies of this Statement are enclosed.
- [ X ] The Commissioner is hereby authorized to charge any deficiency in fees and credit any overpayment to Deposit Account 50-0590. Two copies of this Statement are enclosed.

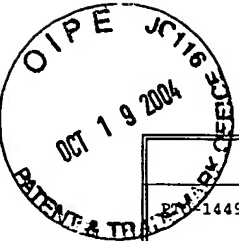
Please note that for the convenience of the Examiner, the entire set of references (AA to EX) listed on the instant PTO-1449 form are included as PDF files on the enclosed compact disc.

Respectfully submitted,  
BIOMEASURE, INCORPORATED

Dated: October 19, 2004

By Pamela C Ball  
Pamela C. Ball, Agent for Applicant(s)  
Registration No.: 53,963

27 Maple Street  
Milford, Massachusetts 01757  
Phone: (508)478-0144  
Facsimile: (508) 473-3531



P-1449 REPRODUCED

ATTORNEY DOCKET NO.  
00537-00900L/007U/APPLICATION NO.  
10/788,563**INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION**

(Use several sheets if necessary)

APPLICANT  
COY, David H., et al.FILING DATE  
February 27, 2004GROUP/EXAMINER  
1614/Unknown**U.S. PATENT DOCUMENTS**

EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA	3,422,083	01/1969	Hess			
	AB	3,862,114	01/1975	Scandrett			
	AC	4,207,311	06/1980	Brown, et al.			
	AD	4,331,661	05/1982	Marki, et al.			
	AE	4,439,360	03/1984	Verdini, et al.			
	AF	4,481,139	11/1984	Folkers, et al.			
	AG	4,501,733	02/1985	Hörig, et al.			
	AH	4,613,586	09/1986	Barchas, et al.			
	AI	4,650,661	03/1987	Szelke, et al.			
	AJ	4,693,993	09/1987	Stewart, et al.			
	AK	4,732,890	03/1988	Bonelli, et al.			
	AL	4,737,487	04/1988	Watts, et al.			
	AM	4,801,613	01/1989	Stewart, et al.			
	AN	4,803,261	02/1989	Coy, et al.			
	AO	4,923,963	05/1990	Stewart, et al.			
	AP	5,068,222	11/1991	Camble, et al.			
	AQ	5,084,555	01/1992	Coy, et al.			
	AR	5,162,497	11/1992	Coy, et al.			
	AS	5,217,955	06/1993	Bogden, et al.			
	AT	5,244,883	09/1993	Cai, et al.			
	AU	5,723,578	03/1998	Coy, et al.			
	AV	5,750,646	05/1998	Coy, et al.			
	AW	5,830,863	11/1998	Buck, et al.			

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**U.S. PATENT DOCUMENTS**

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	AX	5,877,277	03/1999	Coy, et al.			
	AY	6,307,017	10/2001	Coy, et al.			

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AZ	0 045 665	02/1982	EP			
	BA	0 109 142	05/1984	EP			
	BB	0 257 742	03/1988	EP			
	BC	0 309 297	03/1989	EP			
	BD	0 313 158	04/1989	EP			
	BE	0 315 367	05/1989	EP			
	BF	0 334 685	09/1989	EP			
	BG	0 345 990	12/1989	EP			
	BH	0 347 802	12/1989	EP			
	BI	0 434 979	07/1991	EP			
	BJ	0 438 566	07/1991	EP			
	BK	0 468 497	01/1992	EP			
	BL	45497/90	02/1990	JP			
	BM	2-502016	07/1990	JP			
	BN	892 677	12/1989	Finland			
	BO	905 741	05/1991	Finland			
	BP	89/02897	04/1989	WIPO			
	BQ	89/09230	10/1989	WIPO			
	BR	90/01037	02/1990	WIPO			
	BS	90/03980	04/1990	WIPO			

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EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	BY	90/15819	12/1990	WIPO			
	BU	91/02745	03/1991	WIPO			
	BV	91/05563	05/1991	WIPO			
	BW	91/06563	05/1991	WIPO			
	BX	92/02545	02/1992	WIPO			
	BY	92/20707	11/1992	WIPO			
	BZ	93/16105	08/1993	WIPO			
	CA	94/21674	09/1994	WIPO			
	CB	91/16355	10/1991	WIPO			
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
	CC	"Amino acids, peptides, and alkaloids," in <u>Organic Chemistry, 2<sup>nd</sup> Edition</u> , DJ Cram and GS Hammond, eds., pp 607-26. McGraw-Hill Book Company, New York NY, 1964.					
	CD	Alexander, et al., "Effects of bombesin on growth of human small cell lung carcinoma in vivo," 1988. Cancer Res. 48:1439-41					
	CE	Aumelas, et al., "1H and 13C NMR studies of pseudo-peptide analogues of the C-terminal tetrapeptide of gastrin," 1987. Int J Pept Protein Res. 30:596-604					
	CF	Bado, et al., "Possible mediation by luminal somatostatin of bombesin-induced satiety in the cat," 1992. Am J Physiol. 263 (1 Pt 2):R84-8					
	CG	Bardi, et al., "Molecular and crystal structures of two $\beta$ -bend forming monothiated analogues of melanostatin," 1988. Tetrahedron 44:761-9.					
	CH	Broccardo, et al., "Relative potency of bombesin-like peptides," 1975. Br J Pharmacol. 55:221-7					
	CI	Camble, et al., "ICI 216140 and other potent in vivo antagonist analogs of bombesin/gastrin-releasing peptide," in <u>Peptides: Chemistry, Structure and Biology</u> , JE Rivier and GR Marshall, eds., pp 174-6. Proceedings of the 11 <sup>th</sup> American Peptide Symposium, July 9-14, 1989 at La Jolla, CA. ESCOM, Leiden NL, 1990.					
	CJ	Caranikas, et al., "Synthesis and biological activities of substance P antagonists," 1982. J Med Chem. 25:1313-6.					
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	CK	Cowan, A., "New bombesin antagonist shown to have encouraging profile," 1988, Trends Pharm. Sci., 9(1):1-3.	
	CL	Coy, et al., "Progress in the development of competitive bombesin antagonists," 1987. Regulatory Peptides 19:105. (Abstracts of the International Symposium on Bombesin-Like Peptides in Health and Disease, Oct. 13 - 16, 1987 in Rome, IT.)	
	CM	Coy, et al., "Probing peptide backbone function in bombesin," 1988. J Biol Chem. 263:5056-60.	
	CN	Coy, et al., "Solid phase reductive alkylation techniques in analogue peptide bond and side-chain modification," 1988. Tetrahedron 44:835-841	
	CO	Coy, et al., "Progress in the development of competitive bombesin antagonists," 1988. Ann N Y Acad Sci. 547:150-7.	
	CP	Coy, et al., "Short-chain pseudopeptide bombesin receptor antagonists with enhanced binding affinities for pancreatic acinar and Swiss 3T3 cells display strong antimitotic activity," 1989. J Biol Chem. 264:14691-7.	
	CQ	Coy, et al., "Systematic development of bombesin/gastrin-releasing peptide antagonists," 1992. J Natl Cancer Inst Monogr. 13:133-9.	
	CR	Cuber, et al., "Blockade of bombesin receptors with [Leu14-psi(CH2NH)-Leu13] bombesin fails to suppress nutrient-induced CCK release from rat duodenojejenum," 1990. Peptides 11:255-8.	
	CS	Cuttitta, et al., "Autocrine growth factors in human small cell lung cancer," 1985. Cancer Surveys 4:707-727.	
	CT	Cuttitta, et al., "Bombesin-like peptides can function as autocrine growth factors in human small-cell lung cancer," 1985. Nature 316:823-6.	
	CU	Dickinson, et al., "Partial agonist activity of the bombesin-receptor antagonist [Leu14-psi-CH2-NH-Leu13]-bombesin in frog peptic cells," 1988. Biochem Biophys Res Commun. 157:1154-8.	
	CV	Drapeau, et al., "[Phe8psi(CH2-NH)Arg9]bradykinin, a B2 receptor selective agonist which is not broken down by either kininase I or kininase II," 1988. Eur J Pharmacol. 155:193-5.	
	CW	Dubreuil, et al., "Degradation of a tetragastrin analogue by a membrane fraction from rat gastric mucosa," 1987. Drug Des Deliv. 2:49-54.	
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	CX	Dutta, et al., "Antagonists of substance P. Further modifications of substance P antagonists obtained by replacing either positions 7, 9 or 7, 8 and 11 of SP with D-amino acid residues," 1986. J Med Chem. 29:1171-8.	
	CY	Edwards, et al., "Potent pseudopeptide bombesin-like agonists and antagonists. Correlation of ordered conformation of bombesin analogs to receptor activity," 1994. Int J Pept Protein Res. 43:374-83.	
	CZ	Engberg, et al., "A synthetic peptide as an antagonist of substance P," 1981. Nature 293:222-3.	
	DA	Ewenson, et al., "Dehydro keto methylene and keto methylene analogues of substance P. Synthesis and biological activity," 1988. J Med Chem. 31:416-421.	
	DB	Gargosky, et al., "C-terminal bombesin sequence requirements for binding and effects on protein synthesis in Swiss 3T3 cells," 1987. Biochem J. 247:427-32.	
	DC	Harbeson, et al., "Synthesis and biological activity of [psi (CH <sub>2</sub> NH)] analogs of neurokinin A(4-10)," in <u>Peptides: Chemistry, Structure and Biology</u> , JE Rivier and GR Marshall, eds., pp 180-1. Proceedings of the 11 <sup>th</sup> American Peptide Symposium, July 9-14, 1989 at La Jolla, CA. ESCOM, Leiden NL, 1990.	
	DE	Heikkila, et al., "Bombesin-related peptides induce calcium mobilization in a subset of human small cell lung cancer cell lines," 1987. J Biol Chem. 262:16456-60.	
	DF	Heimbrook, et al., "Design and evaluation of novel gastrin-releasing peptide antagonists for the treatment of small cell lung cancer," in <u>Peptides: Chemistry, Structure and Biology</u> , JE Rivier and GR Marshall, eds., pp 56-9. Proceedings of the 11 <sup>th</sup> American Peptide Symposium, July 9-14, 1989 at La Jolla, CA. ESCOM, Leiden NL, 1990.	
	DG	Heinz-erian, et al., "[D-Phe <sup>12</sup> ]bombesin analogues: a new class of bombesin receptor antagonists," 1987. Am J Physiol. 252 (Gastrointest. Liver Physiol. 15):G439-42.	
	DH	Hocart, et al., "Analogues of growth hormone-releasing factor (1-29) amide containing the reduced peptide bond isostere in the N-terminal region," 1990. J Med Chem. 33:1954-8.	
	DI	Jensen, et al., "Characterization of ability of various substance P antagonists to inhibit action of bombesin," 1988. Am J Physiol. 254(6 Pt 1):G883-90.	
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	DJ	Leander, et al., "A specific substance P antagonist blocks smooth muscle contractions induced by non-cholinergic, non-adrenergic nerve stimulation," 1981. Nature 294:467-9.	
	DK	Lehninger, "Amino acids and peptides," in <u>Principles of Biochemistry, 3rd Edition</u> , S Anderson and J Fox, eds., pp 95-120. Worth Publishers, Inc., New York NY, 1982.	
	DL	Leij, et al., "Door recombinant-interleukine-2 gestimuleerde lymfocyten in perifeer bloed als effectorcellen voor de inductie van lysis van cellen bij kleincellig longcarcinoom," May 28, 1988. (Abstract) Ned. Tijdschr Geneesk	
	DM	Lundberg, et al., "A substance P antagonist inhibits vagally induced increase in vascular permeability and bronchial smooth muscle contraction in the guinea pig," 1983. Proc Natl Acad Sci USA 80:1120-4.	
	DN	Mahmoud, et al., "Small cell lung cancer bombesin receptors are antagonized by reduced peptide bond analogues," 1989. Life Sci. 44:367-73.	
	DO	Mahmoud, et al., "[Psi 13,14] bombesin analogues inhibit growth of small cell lung cancer in vitro and in vivo," 1991. Cancer Res. 51:1798-802.	
	DP	Martinez, et al., "Synthesis and biological activities of some pseudo-peptide analogues of tetragastrin: the importance of the peptide backbone," 1985. J Med Chem. 28:1874-9.	
	DQ	Martinez, et al., "Selective cholecystokinin receptor antagonists," in <u>Cholecystokinin Antagonists</u> , RY Wang and R Shoenfeld, eds., pp 29-51. Alan R. Liss, New York NY, 1988.	
	DR	Mizrahi, et al., "Substance P antagonists active in vitro and in vivo," 1982. Eur J Pharmacol. 82:101-5.	
	DS	Nagain, et al., "In vivo activities of peptide and pseudo-peptide analogs of the C-terminal octapeptide of cholecystokinin on pancreatic secretion in the rat," 1987. Peptides 8:1023-8.	
	DT	Payan, "Neuropeptides and inflammation: the role of substance P," 1989. Ann Rev Med. 40:341-52.	
	DU	Plevin, et al., "Multiple B2 kinin receptors in mammalian tissues," 1988. Trends Pharmacol Sci. 9:387-9.	
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	DV	Qian, et al., "Reduced peptide bond pseudopeptide analogues of substance P. A new class of substance P receptor antagonists with enhanced specificity," 1989. J Biol Chem. 264:16667-71.	
	DW	Rivier, et al., "Bombesin, bombesin analogues, and related peptides: effects on thermoregulation," 1978. Biochemistry 17:1766-71.	
	DX	Rivier, et al., "Competitive Antagonists of peptide hormones," 1987. Regulatory Peptides 19:135. (Abstracts of the International Symposium on Bombesin-Like Peptides in Health and Disease, Oct. 13 - 16, 1987 in Rome, IT)	
	DY	Rodriguez, et al., "Synthesis and biological activities of pseudopeptide analogues of the C-terminal heptapeptide of cholecystokinin. On the importance of the peptide bonds," 1987. J Med Chem. 30:1366-73.	
	DZ	Rosell, et al., "Substance P antagonists: a new type of pharmacological tool," 1982. Trends Pharmacol Sci. 3:211-2.	
	EA	Rossowski, et al., "Effects of a novel, potent bombesin antagonist analogue on bombesin-stimulated gastric acid secretion and growth hormone release in the pentobarbital-anesthetized rat," 1988. The Endocrine Society, 70th Annual Meeting, Abstract Supplement, p. 308.	
	EB	Rossowski, et al., "Somatostatin, gastrin, and cholinergic muscarinic binding sites in rat gastric, duodenal, and jejunal mucosa," 1988. Scand J Gastroenterol. 23:717-25.	
	EC	Rossowski, et al., "Effects of a novel bombesin antagonist analogue on bombesin-stimulated gastric acid secretion and growth hormone release in the pentobarbital-anesthetized rat," 1989, Scand J Gastroenterol 24:121-128.	
	ED	Rudinger, J., "Characteristics of the amino acids as components of a peptide hormone sequence," in <u>Peptide Hormones</u> , JA Parsons, ed., pp 1-7. University Park Press, Baltimore MD, 1976.	
	EE	Sakura, et al., "Contractile activity of rat Neuromedin U and its fragments on isolated smooth muscle preparations," in <u>Peptides 1990: Proceedings of the Twenty-First European Peptide Symposium</u> , E Giralt and D Andreu, eds., pp 655-8. ESCOM Science Publishers BV, Leiden NL, 1991.	
	EF	Sasaki, et al., "Solid-phase synthesis and biological properties of psi[CH <sub>2</sub> NH] pseudopeptide analogues of a highly potent somatostatin octapeptide," 1987. J Med Chem. 30:1162-6.	
	EG	Sawyer, et al., "Design, structure-activity, and molecular modeling studies of potent renin inhibitory peptides having N-terminal Nin-For-Trp (Ftr): angiotensinogen congeners modified by P1-P1' Phe-Phe, Sta, Leu psi[CH(OH)CH <sub>2</sub> ]Val or leu psi[CH <sub>2</sub> NH]Val substitutions," 1988. J Med Chem. 31:18-30.	
	EH	Sawyer, et al., "Structure-conformation-activity relationships of renin inhibitory peptides having P1-P1'Xaa-psi[CH <sub>2</sub> NH]Yaa substitutions: molecular modeling and crystallography studies," 1988. Tetrahedron 44:661-73.	
	EI	Schroder, "Structure activity relationships of kinins," E.G. Erdos. ed., 1970. in <u>Handbook of Exp. Pharm.</u> 25:324-50.	
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EJ	Severi, et al., "Pharmacological characterization of [Leu-13-psi-CH <sub>2</sub> NH-Leu14]-bombesin as a specific bombesin receptor antagonist on isolated smooth muscle cells," 1989. J Pharmacol Exp Ther. 251:713-7.		
EK	Spatola, "Peptide backbone modifications: a structure-activity analysis of peptides....," in <u>Chemistry and Biochemistry of Amino Acids, Peptides, and Proteins, A Survey of Recent Developments</u> , Vol. 7, B Weinstein, ed., pp 267-357. Marcel Dekker, Inc., New York NY, 1983.		
EL	Spatola, et al., "Amide bond surrogates: pseudopeptides and macrocycles," 1988. Tetrahedron 44:821-33.		
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